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Legal Sidebar

Recent Supreme Court Decisions Related to E-Cigarette Regulation

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In its most recent term, the Supreme Court considered two cases related to the implementation of the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA, P.L. 111-31) as applied to certain electronic nicotine delivery system products—products commonly known as "e-cigarettes" or "vapes." The Food and Drug Administration (FDA) has generally implemented the TCA to require e-cigarettes to receive prior authorization from FDA before they can be lawfully marketed in the United States. As of January 2025, FDA has authorized 30 tobacco-flavored e-cigarettes and 4 menthol-flavored e-cigarettes for lawful marketing but has not authorized any dessert-, candy-, or fruit-flavored (sweet-flavored) e-cigarettes. Many applicants that have received FDA's marketing denial orders have petitioned for judicial review of those orders. In *FDA v. Wages and White Lion Investments, LLC*, a unanimous Supreme Court largely upheld FDA's denial orders regarding certain applications concerning certain sweet-flavored e-cigarettes but left unresolved one question that the Court remanded to the U.S. Court of Appeals for the Fifth Circuit to consider. In *FDA v. R.J. Reynolds*, the Supreme Court held that e-cigarette retailers—who did not file applications seeking to market e-cigarette products but would sell the products subject to the relevant applications—are persons "adversely affected" under the TCA and may seek judicial review of the relevant denial orders. This Sidebar provides an overview of the relevant statutory and regulatory background and the Court's decisions, and highlights certain considerations for Congress.

Background

TCA's Statutory Framework

Enacted in 2009, the TCA establishes the central federal regulatory regime for the manufacture, marketing, and distribution of tobacco products. Among other things, the TCA requires all new tobacco products—that is, those not commercially marketed in the United States prior to February 15, 2007—to receive prior authorization from FDA before they can be marketed to the public. In establishing this regulatory regime, the TCA aims to balance competing interests in protecting the public's health against the harmful effects of smoking and youth tobacco use, while preserving access to lawfully marketed tobacco products for adult consumers. To further this goal, the TCA generally requires entities seeking to

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market new tobacco products to submit a premarket tobacco product application (PMTA) and receive marketing authorization from FDA.

The TCA requires FDA to deny a PMTA upon certain findings, including a conclusion that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health [APPH]." This APPH determination must be made "with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," taking into account the "likelihood that existing users of tobacco products will stop using such products" and the likelihood that consumers who do not use such products will start using them. The TCA directs FDA to consult a range of evidence when making this evaluation, including "information submitted to the Secretary as part of the [PMTA]." Such information may include, "when appropriate, . . . well-controlled investigations" as well as other "valid scientific evidence" determined by the Secretary to be "sufficient to evaluate the tobacco product."

The TCA's judicial review provision permits "any person adversely affected" by a denial of a PMTA to file a petition for review of the denial order with the U.S. Court of Appeals for the D.C. Circuit or the circuit in which "such person resides or has their principal place of business."

While the TCA explicitly applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, the statute also authorizes FDA to deem other tobacco products subject to the law.

FDA Regulatory Actions Related to E-Cigarettes

E-cigarettes are products that deliver nicotine to their users by heating an "e-liquid"—which usually contains nicotine derived from tobacco, flavorings, and other additives—to create an inhalable aerosol. These products come in an array of device types and flavors, from tobacco and menthol flavors based on the flavors of traditional combustible cigarettes to other sweet-flavored varieties. E-cigarettes first began appearing on the U.S. market during the mid-2000s, and their sales increased rapidly in the 2010s, including to youth, who reported high use of sweet-flavored e-cigarettes in several surveys. By 2015, e-cigarettes surpassed combustible cigarettes as the nicotine product of choice among U.S. high school students. Around the same time, limited testing of certain e-cigarettes showed that they contained substantially lower levels of toxins than combustible cigarettes, indicating their potential to reduce health risks to individuals who completely switch from using combustible cigarettes to using e-cigarettes.

In 2016, FDA invoked its authority under the TCA and promulgated what is known as the "deeming rule," which subjected e-cigarettes to the TCA's regulatory regime. Under the rule, entities seeking to legally market e-cigarettes that were on the market as of August 8, 2016, or any new e-cigarette products, were generally required to submit a PMTA. For e-cigarette products that were already on the market, the submission deadline ultimately fell on September 9, 2020. FDA stated that it would defer enforcement against these products for a specified period to allow applicants to prepare their applications.

Before the PMTA submission deadline, FDA communicated to applicants its expectations regarding their submissions through various documents, including (1) June 2019 guidance outlining the agency's then-current "thinking on the types of information an applicant should include in a PMTA" to help the agency make the APPH determination; (2) a September 2019 proposed rule (not finalized until after the submission deadline) that would, among other things, "interpret and set forth requirements related to the content and format of PMTAs," including health risk investigations and other information like marketing plans that describe relevant sales restrictions that would prevent youth access; and (3) April 2020 guidance describing FDA's enforcement priorities related to "flavored, cartridge-based" e-cigarettes and any e-cigarette that is marketed in a manner that is likely to promote use by minors. In general, these documents did not define the specific studies that must be included in a PMTA, to the extent that they addressed such studies. While they noted that the agency did not expect applicants to conduct long-term studies, they also emphasized that the APPH determination would be based on review of "valid scientific

evidence" in the application, including evidence comparing the health risks of the products at issue with those of other products within the same category.

By the September 9, 2020, PMTA deadline, FDA received applications for more than 6 million products. To manage review of these applications, FDA circulated and rescinded several internal memoranda that sought to describe the agency's review process. These documents included a July 2021 memorandum stating that an application would "likely receive a marketing denial order" if it did not include either a randomized controlled trial or a longitudinal cohort study. An August 2021 superseding memorandum explained that the agency would broaden its review to consider other types of studies if they "reliably and robustly assess behavior change (product switching or cigarette reduction) over time, comparing users of flavored products with those of tobacco-flavored products."

As of January 2025, FDA has authorized certain tobacco- and menthol-flavored e-cigarettes for lawful marketing. With respect to those products, the agency generally concluded that they were APPH because they can help adult smokers switch to less harmful tobacco products. FDA has not authorized any sweet-flavored e-cigarettes because the agency determined that the applications for such products to date "lacked sufficient evidence that the benefit to adult smokers who used the flavor products would overcome the public health concern posed by the well-documented and considerable appeal of the products to youth."

Relevant Litigation History

Wages and White Lion Investments, LLC (doing business as Triton Distribution) and Vapetasia, LLC—manufacturers of e-liquids used in refillable (i.e., non-cartridge-based) e-cigarettes—were among the entities that sought authorization to market e-liquids in sweet flavors such as "Suicide Bunny Mother's Milk and Cookies" and "Iced Pineapple Express." In September 2021, FDA denied marketing authorization for the products at issue, concluding that authorizing the products would not be APPH because the applications did not include "acceptably strong evidence that the flavored products have an added benefit relative to that of tobacco-flavored" e-cigarettes that would outweigh the risks they pose. Upon making this determination, FDA declined to evaluate the manufacturers' marketing plans, which outlined strategies to restrict youth access, given FDA's prior observations that no restrictions to date have successfully reduced youth access. The manufacturers filed petitions with the Fifth Circuit for review of FDA's denial orders.

An en banc Fifth Circuit—deviating from most other circuits that had considered similar petitions—held that FDA's denial orders were arbitrary and capricious, in violation of the Administrative Procedure Act (APA). In particular, the court held that FDA, in reviewing the manufacturers' applications, changed its position regarding the review standard it said it would apply in predecisional guidance in several respects. According to the court, contrary to FDA's predecisional guidance, which stated that long-term studies were not expected, FDA ultimately required the manufacturers to submit (1) randomized controlled trials or longitudinal cohort studies and (2) studies that compare sweet-flavored e-cigarettes and tobacco-flavored e-cigarettes in their ability to promote switching from more harmful tobacco products. The court additionally concluded that in denying the manufacturers' applications, FDA also changed its position regarding its previously stated (1) focus on cartridge-based device types for sweet-flavored e-cigarettes and (2) emphasis on the inclusion of marketing plans in the PMTA. The agency's "about-face" on these issues, according to the court, was not preceded by adequate notice or accompanied by justification, rendering the resulting denial orders arbitrary and capricious. With respect to FDA's decision not to review the manufacturers' marketing plans, the court further held that the error was not harmless. In the court's view, the harmless-error rule—which generally permits a court to uphold an agency decision despite an error if the court can determine that the outcome would be the same absent the error—could not apply to discretionary administrative decisions such as the PMTA review at issue.

While Wages and White Lion's petition was pending for en banc review, R.J. Reynolds—another manufacturer that unsuccessfully applied for authorization to market berry- and menthol-flavored e-cigarettes—sought judicial review of its denial order; certain retailers of e-cigarette products joined R.J. Reynolds' petition. R.J. Reynolds has its principal place of business in North Carolina, which is located in the Fourth Circuit. Had the manufacturer petitioned for review alone, TCA's judicial review provision would have limited the petition to be filed in either the D.C. Circuit or the Fourth Circuit—two circuits that had already ruled in favor of FDA in petitions raising similar challenges. The petitioners instead sought review in the Fifth Circuit, where two of the retailer petitioners are based. On FDA's motion to dismiss the petition or to transfer venue, a divided panel denied the motion, concluding that the retailers are "person[s] adversely affected" for purposes of TCA's judicial review provision.

FDA sought Supreme Court review of the Fifth Circuit's decisions in both *Wages and White Lion* and *R.J. Reynolds*, and the Court granted the respective petitions for certiorari.

The Supreme Court's Opinion in *FDA v. Wages and White Lion Investments, LLC*

In *FDA v. Wages and White Lion Investments*, a unanimous Supreme Court largely reversed the Fifth Circuit. In the Court's view, the Fifth Circuit's conclusion that FDA's denial orders were arbitrary and capricious orbits around one key concern—that "FDA told [applicants] in guidance documents that it would do one thing and then turned around and did something different when it reviewed their applications." In particular, the Court observed that the Fifth Circuit decision reflected concerns around four overarching topics: (1) whether FDA told applicants that they would not need to provide specific kinds of scientific studies like randomized controlled trials or longitudinal cohort studies but ultimately treated such evidence as essential; (2) whether FDA told applicants they could show the benefits of their e-cigarettes by comparing them to tobacco products of their choosing but ultimately required applicants to compare the benefits of their sweet-flavored e-cigarettes with those of tobacco-flavored e-cigarettes; (3) whether FDA told applicants it would treat non-cartridge-based flavored e-cigarettes differently from cartridge-based flavored e-cigarettes; and (4) whether FDA told applicants that marketing plans were "essential" but ultimately refused to review them. After "a close reading of nuanced statements in a body of guidance documents that evidence the agency's evolving assessment of the relevant issues," the Court concluded that the "FDA's denial orders were sufficiently consistent with its predecisional guidance" as to the first three topics on scientific evidence, cross-flavor comparisons, and device type.

The Court explained that the relevant administrative law principle at issue is the change-in-position doctrine. Under the doctrine, the Court observed that it "must ask whether the FDA changed course and, if it did, whether it offered satisfactory reasons for the change." Applying this review, the Court found that FDA denied the manufacturers' applications consistent with the guidance's recommendation that applications should be supported by adequately rigorous scientific evidence in the absence of randomized controlled trials or longitudinal cohort studies. Similarly, while the Court agreed that FDA did not provide a precise instruction regarding the type of comparative efficacy studies needed, it noted that the TCA does not require such specificity. Instead, the Court concluded that FDA has discretion to develop this standard through adjudicating applications and that the standard applied by FDA is also consistent with the TCA and FDA's ongoing concern—reflected in predecisional guidance—regarding sweet-flavored e-cigarette's appeal to youth. Finally, as to device type, the Court observed that while certain FDA predecisional guidance "unmistakably emphasized cartridge-based products," nothing in the guidance—which also reflected a general concern about e-cigarettes' appeal to youth—provided a "safe harbor" from enforcement to non-cartridge-based products. Thus, in the Court's view, the denial orders do not reflect any change in scope of enforcement activity. Accordingly, the Court concluded that FDA did not

"improperly change[] its position with respect to scientific evidence, comparative efficacy, or device type."

With respect to FDA's failure to review the manufacturers' marketing plans, the Court noted that FDA did not seek review of this finding of error. Instead, FDA sought review of the Fifth Circuit's holding that the harmless-error rule could not apply. In the Fifth Circuit's view, the harmless-error rule can apply only if the agency, upon remand, would be "*required* to take the same action no matter what." Agreeing with FDA, the Court held that this formulation of harmless error was too narrow. The Court noted that the harmless-error rule can apply, for instance, when the error pertains to a factual finding that is among "a plethora of factual findings" without error that support an agency's decision or "[w]hen it is clear that the agency's error 'had no bearing on the procedure used or the substance of [the] decision reached.'" At the same time, the Court, quoting Judge Henry Friendly, cautioned that "[w]here the agency has rested decision on an unsustainable reason, the court should generally reverse and remand even though it discerns a possibility, *even a strong one*, that by another course of reasoning the agency might come to the same result." With these clarifications on the harmless-error rule, the Court remanded the case to the Fifth Circuit to determine afresh whether FDA's failure to review the manufacturers' marketing plans was harmless error.

The Court also declined to address several questions that it considered to be inadequately briefed and outside the scope of the questions presented, including whether relevant law requires FDA to use notice-and-comment rulemaking to set out PMTA requirements and whether the relevant TCA provisions are unconstitutionally vague.

The Supreme Court's Opinion in *FDA v. R.J. Reynolds*

In *FDA v. R.J. Reynolds*, the Supreme Court, in a 7-2 decision, held that retailers—who did not file applications seeking FDA's authorization to market e-cigarette products but would sell the products subject to the relevant applications—are persons "adversely affected" by FDA's denial orders with respect to such applications. Accordingly, the Court held that such retailers may seek judicial review of the relevant denial orders under the TCA. The Court thus ruled that the Fifth Circuit correctly concluded that with respect to the petition related to R.J. Reynolds's e-cigarette products, two of the retailer petitioners can properly establish venue in the Fifth Circuit.

In the Court's view, the TCA's judicial review provision authorizing "any person adversely affected" by FDA's denial order to petition for judicial review of a denial order "carries the same meaning" as in the APA. Under the APA, this standard is "not especially demanding" and permits plaintiffs to sue unless their "interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." Applying this standard to the TCA, the Court reasoned that the TCA's "zone of interest" extends "to any petitioner with an interest arguably sought to be protected by the statute" (internal quotation marks omitted). Retailers who "lose the opportunity to profit from the sale" of the relevant e-cigarette product, or "risk imprisonment and other sanctions" if they sell the products, the Court concluded, "fit the bill." In so concluding, the Court rejected FDA's argument that "only a disappointed applicant" is "adversely affected" under the TCA.

In the Court's view, the conclusion that retailers are among "person[s] adversely affected" is consistent with Congress's use of "any"—a term with an expansive meaning—to refer to "person adversely affected," a phrase that itself already "suggests an intent to cover more than one party." The Court further observed that "Congress knows how to limit the scope of a cause of action," as reflected in a different provision in the TCA that allows only the "holder of [the] application" to challenge FDA's order to withdraw an existing authorization that permits the lawful marketing of a new tobacco product. The Court reasoned that the use of these different terms reflects a specific choice by Congress and rejected FDA's argument that "Congress would not have allowed retailers to challenge denial orders (in which they

normally have no reliance interests) but not withdrawal orders (in which they usually have significant reliance interests).” The Court declined to address FDA’s additional argument, raised for the first time before the Court, that even if retailers can petition for judicial review, each petitioner in a joint petition must independently establish venue.

Justice Jackson issued a dissenting opinion, joined by Justice Sotomayor. The dissent agreed with the majority that the relevant inquiry turns on the TCA’s “zone of interest.” In the dissent’s view, however, the inquiry, in order to “[t]o properly discern congressional intent about the breadth of [the TCA’s] cause of action,” must focus not on the judicial review provision itself but on the cross-referenced provision that defines the statutory scheme establishing the relevant application and review process. According to the dissent, analysis of that provision “reveals that [it] is part of a statutory scheme that establishes an adjudicatory process between a manufacturer and the FDA—and no one else.” Because this “detailed scheme for manufacturers to obtain authorization to market new tobacco products” is one “within which retailers have no rights and play no role,” the dissent reasoned, nothing in the TCA “suggests that Congress meant to authorize retailers to sue to challenge the FDA’s denial of a manufacturer’s marketing application, much less bring that legal challenge in a venue that is otherwise unavailable.” In the dissent’s view, the majority’s interpretation “not only opens up an avenue for judicial review that Congress did not intend, it also allows manufacturers like [R.J. Reynolds] to evade the statute’s venue requirements.”

Considerations for Congress

Wages and White Lion and *R.J. Reynolds* each resolved important questions related to the TCA’s implementation: The former largely approved the standard by which FDA has reviewed applications related to sweet-flavored e-cigarettes, while the latter clarified that retailers who would sell a new tobacco product may seek judicial review of a marketing denial order. Each case, however, also left unresolved questions that may be the subject of further litigation. In *Wages and White Lion*, for instance, the Court did not resolve whether FDA’s decision not to review applicants’ marketing plan was harmless error, nor whether relevant law—including under the TCA and APA—requires FDA to develop the applicable review standards through rulemaking rather than through adjudication, as the agency has done to date. In *R.J. Reynolds*, the Court did not resolve FDA’s argument that each petitioner in a joint petition must independently establish venue. If FDA chooses not to press this venue question in further litigation, that would likely mean that, as a practical matter, applicants can generally file petitions for review in a venue of their choosing by joining relevant retailers. Because the Fifth Circuit has issued opinions most favorable to petitioners to date, it may be likely that, going forward, petitioners seeking to challenge FDA’s denial orders will strategically join relevant retailers to file petitions in that circuit.

Most of the questions raised by this pair of e-cigarette cases center around the interpretation of the TCA and relevant congressional intent—including questions regarding the applicable review standards, how FDA may set forth such standards, and who may petition for judicial review of a denial order. Because these are ultimately questions of congressional intent, Congress may respond to the Court’s decisions as it determines appropriate. Such responses may include clarifying the relevant review standards for e-cigarettes (or sub-categories of e-cigarettes), the process by which such standards may be set, who may challenge FDA’s denial orders, and where and how such petitions must be filed.

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